DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 22, 2014

Neodent USA Incorporated
Christopher Klaczyk
Director of Regulatory Affairs
60 Minutemen Road
Andover, MA 01810

Re: K133592
Trade/Device Name: Neodent Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 24, 2014
Received: July 25, 2014

Dear Mr. Klaczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications For Use

510(k) Number (if known): _____

Device Name: Neodent Implant System

Indications for Use:

The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(k) Summary

Manufacturer:
JJGC Indústria e Comércio de Materiais Dentários SA
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Establishment Registration No. Pending

Date Prepared: November 21, 2013

Product Code(s): DZE (21 CFR 872.3640)

Device Class: II (21 CFR 872.3640)

Classification Panel: Dental Devices

Classification Name: Endosseous dental implant

Proprietary Name: Neodent Implant System

Predicate Device(s): Neodent Implant System is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

- JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K101207
- JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K101945
- JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K123022
- JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K133510
- Institut Straumann AG, SLActive Implants, K033984

Device Description: The subject **Titamax Ti EX Acqua** implants are provided in the same design variants as the predicate Titamax Ti EX implants. The only difference is the application of the Acqua hydrophilic surface treatment in place of the NeoPoros surface finish. The Titamax Ti EX Acqua are provided in two endosseous diameters (3.75 and 4.0 mm), one platform diameter (4.1 mm), and five lengths (9, 11, 13, 15, and 17 mm).

The subject **Ti Drive Acqua** implants have the same tapered, single thread design variants as the predicate CM Drive implants and the same external hex abutment interface and internal geometry as the predicate HE series implants. They also have the Acqua hydrophilic surface treatment in place of the NeoPoros surface finish. The Ti Drive Acqua implants are provided in three endosseous diameters (3.5, 4.3, and 5.0 mm), three platform diameters (3.3, 4.3, and 5.0 mm), and five lengths (8, 10, 11.5, 13, and 16 mm).

The subject **Titamax CM EX Acqua** implants are provided in the same design variants as the predicate Titamax CM EX implants. The only difference is the application of the Acqua hydrophilic surface treatment in place of the NeoPoros surface finish. The Titamax CM EX Acqua implants are provided in three endosseous diameters (3.5, 3.75, and 4.0 mm), three platform diameters (3.5, 3.75, and 4.0 mm), and five lengths (9, 11, 13, 15, 17 and 19 mm).

The subject **CM Drive Acqua** implants are provided in the same design variants as the predicate Titamax CM EX implants. The only difference is the application of the Acqua hydrophilic surface treatment in place of the NeoPoros surface finish. The CM Drive Acqua implants are provided in three endosseous diameters (3.5, 4.3, and 5.0 mm), three platform diameters (3.3, 4.3, and 5.0 mm), and five lengths (8, 10, 11.5, 13, and 16 mm).

The subject **Titamax Smart EX Acqua** implants are provided in the same design variants as the predicate. The only difference is the application of the Acqua hydrophilic surface treatment in place of the NeoPoros surface finish. The Titamax Smart EX Acqua implants are provided in two endosseous diameters (3.75 and 4.0 mm), one platform

diameter (4.1 mm), and five lengths (9, 11, 13, 15, and 17 mm).

The subject device **Drive Smart Acqua** implants are provided in the same design variants as the predicate Drive Smart implants. The only difference is the application of the Acqua hydrophilic surface treatment in place of the NeoPoros surface finish. The Drive Smart Acqua implants are provided in three endosseous diameters (3.5, 4.3, and 5.0 mm), three platform diameters (3.3, 4.3, and 5.0 mm), and five lengths (8, 10, 11.5, 13, and 16 mm).

The Acqua surface finish is a traditional grit blast and acid etch surface that is further processed in a manner that renders it hydrophilic.

Intended Use: The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.

Materials: The subject implant devices are made of Grade 4 commercially pure titanium conforming to ASTM F67, *Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)*, with a surface that is grit blasted, acid etched and subjected to a process that renders them hydrophilic. The subject Smart mount devices are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*

Performance Data: Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include engineering analysis and dimensional analysis. Bench testing and animal testing were submitted to characterize the Acqua surface. The data included in this submission demonstrate substantial equivalence to the referenced predicate devices.

Clinical data were not submitted in this premarket notification.

Conclusions: The implants of the subject Neodent Implant System have a similar design and dimensions, use similar materials and have a similar surface topology as those cleared under K101207, K101945, K123022 and K133510. The Acqua hydrophilic surface treatment is similar to the SLActive surface cleared in K033984.

Based upon our assessment of the performance data, the subject device is safe and effective for its intended use and performs as well as the referenced predicate device(s).